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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 18 1989

Re: Ceradon
Docket Nos. 89E-0086,-0087

SOLICITOR
OCT 20 1989
U.S. PATENT & TRADEMARK OFFICE

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension applications for U.S. Patent Nos. 4,241,057 and 4,161,527 filed by Takeda Chemical Industries, Ltd. under 35 U.S.C. 156. The patents claim the human drug product Ceradon, New Drug Application 50-601.

In the April 13, 1989, issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before October 10, 1989, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. FDA, therefore, considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Douglas P. Mueller
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